UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
CHARLOTTESVILLE DIVISION

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PBM PHARMACEUTICALS, INC.

Plaintiff,

Civil Action No. _____

v.

METHOD PHARMACEUTICALS, LLC
AND JOHN DOES 1-2

Defendants.

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COMPLAINT

Plaintiff PBM Pharmaceuticals, Inc. ("Plaintiff"), by and through its undersigned counsel, for its Complaint against Defendants Method Pharmaceuticals, LLC and John Does 1-2 ("Defendants"), hereby alleges and states the following:

INTRODUCTION

1. For nearly 80 years, Plaintiff's Donnatal® brand of pharmaceutical products has helped improve the lives of individuals suffering from irritable bowel syndrome (IBS), a condition characterized by abdominal pain, bloating, and irregular diarrhea or constipation.

2. Plaintiff distributes and markets Donnatal in two unique formulations: (1) immediate release Donnatal Tablets and (2) fast-acting Donnatal Elixir, available in either grape or mint flavor.

3. The active formulation in Donnatal comprises a combination of phenobarbital and belladonna alkaloids ("PBA").

4. Defendants saw an opportunity to exploit the success of Donnatal® by creating a knock-off PBA product that it is calling "Me-PB-Hyos." Defendants falsely represent that Me-PB-Hyos is available in tablet and elixir form, and functions as a generic substitute for Donnatal.

5. Plaintiff brings this action for injunctive relief to stop Defendants from falsely representing Me-PB-Hyos as a therapeutic equivalent to Donnatal. Plaintiff also seeks damages resulting from Defendants' unlawful conduct, including damages for harm to Plaintiff's reputation and goodwill.

THE PARTIES

6. Plaintiff PBM Pharmaceuticals, Inc., conducting business under the name Revive Pharmaceuticals, is a Delaware corporation having its principal place of business in Charlottesville, Virginia. Plaintiff is a rapidly growing specialty pharmaceutical company that focuses on revitalizing popular pharmaceutical products placed into lifecycle management by larger pharmaceutical companies.

7. Upon information and belief, Defendant Method Pharmaceuticals, LLC ("Method") is a Texas limited liability company with its principal office at 2000 East Lamar Boulevard, Suite 200, Arlington, Texas 76006. Method is the labeler for the Me-PB-Hyos products.

8. The identity of Defendants John Does 1-2 is unknown. John Does 1-2 are the manufacturer and distributor of the Me-PB-Hyos products.

JURISDICTION

9. This Court has subject matter jurisdiction over the claims pursuant to 28 U.S.C. §§ 1331 and 1338. The Court also has supplemental jurisdiction over the Plaintiff's state and common law claims pursuant to 28 U.S.C. § 1367.

10. Venue is proper in this district pursuant to 28 U.S.C. § 1391. A substantial part of the events giving rise to the claims against Defendants occurred in this District.

11. This Court has personal jurisdiction over Defendants because the Defendants have listed their products for sale in an online database that is used by purchasers of PBA pharmaceuticals in this District, and, accordingly, Defendants have purposefully directed their business activities toward this District. In addition, the Defendants have caused harm to Plaintiff in this District. Through such conduct, Defendants have purposefully availed themselves of the privileges of conducting business in this District, and, when engaging in such conduct, it was reasonably foreseeable that Defendants would be subjected to this Court's jurisdiction.

BACKGROUND FACTS

12. According to the National Institute of Health, as many of 30% of Americans suffer from IBS at some point in their lives. IBS can severely compromise an individual's quality of life, and is second only to the common cold as a cause of absenteeism from work.

13. Donnatal® is a proprietary combination medicine used as adjunctive therapy in the treatment of IBS, as well as acute enterocolitis. Because Donnatal® requires use under the supervision of a healthcare provider, it is available by prescription only.

14. The Donnatal® products were first introduced in the market by A.H. Robins Company ("Robins") in 1936. Plaintiff is the successor-in-interest to Robins, and has owned and marketed the Donnatal products since 2001.

15. In 1962, when Congress amended the Federal Food, Drug and Cosmetic Act ("FD&C Act"), the Food and Drug Administration (FDA) was required to conduct a retrospective evaluation of drugs that had previously been approved under the FD&C Act between its enactment in 1938 and 1962. Donnatal® was one of more than 3,400 drugs affected by this amendment. 21 U.SC. § 301 et seq.

16. In the 1970s, the FDA began a process of evaluating the safety and efficacy of PBA drug products under the Drug Efficacy Study Implementation ("DESI") review program. On June 20, 1978, the FDA required any drugs that were involved in the review process to obtain an approved New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA") to remain on the market. 43 Fed. Reg. 26,490 (June 20, 1978).

17. On December 30, 1980 Plaintiff's predecessor, Robins, obtained conditional approval ANDAs for its Donnatal Tablets (ANDA 88-676) and Donnatal Elixir (ANDA 86-661). Conditionally approved ANDAs have the same status as safety-only NDAs that had been approved prior to the 1962 Amendments. Drug products manufactured under such a conditionally approved ANDA can be legally marketed until the FDA resolves questions about their effectiveness under the FD&C Act.

18. On May 6, 1983, the FDA published in the Federal Register a notice of an opportunity for a hearing ("NOOH") regarding the regulatory status of PBA drug products, including Donnatal. Under the FD&C Act, FDA requires the holders of approved NDAs or

those alleging such approvals to submit clinical evidence within 60 days of the NOOH showing that genuine and material issues of fact exist about the effectiveness of the drug that require an administrative hearing for resolution.

19. In response to the NOOH, Robins submitted substantial clinical evidence that raised genuine and material issues supporting the effectiveness of Donnatal.

20. Under the NOOH process, only those companies that actively participated in this hearing process were permitted to legally market their PBA drug products. Plaintiff's Donnatal products have been under this NOOH since 1983, and thus have been allowed to continue to remain on the market pending final resolution of the hearing process. The hearing process for PBA products has not yet been completed.

21. In July 2011, in response to a notice from the FDA seeking clarification of the ownership of Donnatal, Plaintiff submitted information demonstrating that Plaintiff is the successor-in-interest to Robbins, and additional substantial clinical evidence and data supporting the effectiveness of the Donnatal products. This submission further clarified Plaintiff's legal basis for marketing its products.

22. Upon information and belief, Plaintiff is the only company that continues to participate in the FDA DESI review process for PBA products.

23. In September 2011, FDA established a Compliance Policy Guide confirming that any drug product coming to market for the first time after September 19, 2011 alleging any legal status under the DESI review was illegal and subject to immediate legal action by the FDA.

24. Accordingly, upon information and belief, Plaintiff is the only company that is legally permitted to market PBA products.

DEFENDANTS' UNLAWFUL CONDUCT

25. On or around April 2, 2014, a listing for Defendants' "Me-PB-Hyos Oral Elixir" and "Me-PB-Hyos Oral Tablets" appeared in medical database Medi-Span. The Me-PB-Hyos pharmaceuticals allege to contain ingredients identical as those included in Plaintiff's Donnatal products, and the listing even includes a cross-reference to Plaintiff's Donnatal products. A copy of the Medi-Span listing is attached as Exhibit A.

26. Medi-Span is a prescription drug information and interactions database used nationwide by health care professionals, payers and pharmaceutical manufacturers to evaluate medications that are currently or will soon be on the market. A listing in such a database of a drug that contains the same active ingredients as another is a statement that the new product is legally marketed and that it is bioequivalent to the reference product to which it refers. In order to be listed in Medi-Span, an applicant must normally submit an FDA Approval Letter and the corresponding approval number. *See* Exhibit B.

27. The Defendants' cross-reference to Plaintiff's Donnatal product is a claim that Plaintiff's product is bioequivalent to Donnatal. Bioequivalence is the basis for a claim that a product is suitable for generic substitution.

28. The FDA would not have provided an Approval Letter or approval number to Defendants because the defendants do not have an approved NDA or ANDA for their drug products, nor are they participants in FDA DESI review process for PBA products.

29. In order to be listed as a DESI unapproved drug product, a Medi-Span applicant must show that the drug product may be legally marketing under the FD&C Act. Upon information and belief, Defendants have not submitted any data showing that the Me-PB-Hyos product is effective pursuant to the NOOH record.

30. The Defendants' products were not marketed until after September 19, 2011.

31. By virtue of being listed in Medi-Span, Defendants are falsely representing that the "Me-PB-Hyos Oral Elixir" and "Me-PB-Hyos Oral Tablets" have been approved for sale by the FDA or are legally marketed DESI products. Defendant Method is listed as the labeler for the Me-PB-Hyos products.

32. The Medi-Span listing does not name the manufacturer(s) and distributor(s) for the drugs, who have been named as Defendants John Does 1 and 2 in this action. Upon information and belief, John Does 1 and 2 have either manufactured and distributed Me-PB-Hyos products, or have agreed to take such actions in the future.

33. By virtue of the listing, Defendants are making a claim that their Me-PB-Hyos products are supported by bioequivalence data showing the products have the same rate and extent of absorption as Donnatal. No data exist showing that the Me-PB-Hyos products are bioequivalent to Donnatal's products, i.e. that the active ingredients in Me-PB-Hyos are absorbed from the drug product and become available at the site of action as the active ingredients in Donnatal.

34. Defendants' listing of their Me-PB-Hyos products has been made available to Plaintiff's customers in this District and has adversely impacted Plaintiff's sales of its Donnatal

products in this District, as purchasers are delaying purchases of Plaintiff's products in favor of Defendants' potentially cheaper PBA products.

35. Defendants' listing of PBA pharmaceuticals that falsely claim to be therapeutically equivalent to Plaintiff's Donnatal products is prohibited by law, has caused irreparable injury to Plaintiff, and will continue both to damage Plaintiff and to deceive and potentially harm the public unless enjoined by this Court.

36. When the false listing came to Plaintiff's attention, Plaintiff promptly contacted Defendant Method regarding its unlawful conduct. In response, Defendant claimed that PBA pharmaceuticals are available to be marketed by anyone, and that Plaintiff does not possess the exclusive rights to market these products.

37. Plaintiff has been and will be harmed by Defendants' literal and implied false and misleading advertising and unfair competition. Defendants' efforts have and will continue to mislead consumers into believing that Me-PB-Hyos is therapeutically equivalent to and may be used interchangeably with Donnatal. Defendants' efforts have harmed and will continue to harm Plaintiff's unique brand, which purchasers of PBA pharmaceuticals have come to recognize as the only FDA-approved entity currently allowed to market PBA pharmaceuticals.

COUNT I

FALSE ADVERTISING IN VIOLATION OF LANHAM ACT SECTION 43(a) (15 U.S.C. § 1125(a))

38. Plaintiff repeats and re-alleges each and every allegation contained in the preceding paragraphs of this Complaint, and incorporates them herein by reference.

39. Defendants' listing of Me-PB-Hyos as FDA-approved, PBA products that are cross-referenced with Plaintiff's Donnatal pharmaceuticals based on having the same active ingredients is a false or misleading representation of fact.

40. Defendants' statement has actually deceived or has the tendency to deceive a substantial segment of its audience.

41. Defendants' implied claim that its goods are therapeutically equivalent to Plaintiff's Donnatal pharmaceuticals is material and likely to influence the purchasing decisions of health care professionals and patients who consume Plaintiff's products.

42. Defendants' false and misleading representations were and are made in interstate commerce.

43. Defendants' listing of misleading representations is in direct violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), which provides in relevant part that "[a]ny person who, in connection with any goods or services...uses in commerce any…false or misleading representation of fact, which in commercial advertising or promotion, misrepresents the nature, characteristics, qualities or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is likely to be damaged by such act."

44. As a direct and proximate result of Defendants' breaches, Plaintiff has suffered and is continuing to suffer irreparable injury, including irreparable injury and damages, which includes a loss of sales and profits, which Plaintiff would have made but for the false and deceptive representations by Defendants.

45. Pursuant to 15 U.S.C. § 1116, Plaintiff is entitled to preliminary and permanent injunctive relief to Defendants' continuing acts.

COUNT II

UNFAIR COMPETITION IN VIOLATION OF LANHAM ACT SECTION 43(a)

(15 U.S.C. § 1125(a))

46. Plaintiff repeats and re-alleges each and every allegation contained in the preceding paragraphs of this Complaint, and incorporates them herein by reference.

47. Plaintiff's Donnatal has become uniquely associated with and identifies Plaintiff as the only FDA-approved provider of PBA pharmaceuticals.

48. Defendants' representation that Me-PB-Hyos is comparable or equivalent to Donnatal, and is an FDA-approved PBA pharmaceutical, has deceived, misled and confused consumers and enabled Defendants to trade off of Plaintiff's reputation and goodwill.

49. Defendants' acts constitute unfair competition in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

50. By reason of Defendants' conduct, Plaintiff has suffered and will continue to suffer damage to its business, reputation and goodwill.

51. Pursuant to 15 U.S.C. § 1117, Plaintiff is entitled to damages for Defendants' Lanham Act violations.

52. Defendants' acts are willful, wanton and calculated to deceive, and are undertaken in bad faith, making this an exceptional case entitling Plaintiff to recover additional damages and its reasonable attorney fees pursuant to 15 U.S.C. § 1117.

53. Defendants' conduct has caused, and unless enjoined by this Court, will continue to cause immediate and irreparable harm to Plaintiff for which there is no adequate remedy at law. Accordingly, Plaintiff is additionally entitled to injunctive relief.

COUNT III

TORTIOUS INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE

54. Plaintiff repeats and re-alleges each and every allegation contained in the preceding paragraphs of this Complaint, and incorporates them herein by reference.

55. Defendants are aware the Plaintiff is the only entity that the FDA has permitted to market and sell PBA products.

56. The conduct of Defendants described above is intended to disrupt the economic relationships between Plaintiff and its customers.

57. Upon information and belief, Plaintiff's customers have limited their purchase of Donnatal pharmaceuticals in anticipation of Defendants' Me-PB-Hyos products.

58. As a proximate result of Defendants' intentional misconduct, Plaintiff has suffered damages in an amount to be proven at trial.

59. The conduct of Defendants in interfering with Plaintiff's economic relationships was intentional, willful and calculated to cause damage to Plaintiff's lawful business. The conduct of Defendants was perpetrated with actual malice and ill will toward Plaintiff, and with the intentional and improper purpose of causing damage. There was no justifiable cause for Defendants' action other than to divert revenue, and as a result, an award of punitive damages is warranted.

COUNT IV

COMMON LAW CIVIL CONSPIRACY

60. Plaintiff repeats and re-alleges each and every allegation contained in the preceding paragraphs of this Complaint, and incorporates them herein by reference.

61. Defendants entered into an agreement and/or understanding, and otherwise conspired with one another and others as yet unnamed, to tortuously interfere with Plaintiff's lawful business and misrepresent to the public that it is legally permitted to sell PBA products.

62. As a result of Defendants' actions, Plaintiff has suffered and is continuing to suffer irreparable injury, including irreparable injury and damages, which includes a loss of sales and profits which Plaintiff would have made but for the acts committed in pursuance of the conspiracy.

COUNT V

VIRGINIA BUSINESS CONSPIRACY

(Va. Code § 18.2-500)

63. Plaintiff repeats and re-alleges each and every allegation contained in the preceding paragraphs of this Complaint, and incorporates them herein by reference.

64. Defendants have associated, agreed, mutually undertaken or acted in concert together for the purpose of willingly or maliciously harming Plaintiff's legal business. Specifically, Defendants have conspired to falsely represent to the public that they are authorized by the FDA to promote and sell PBA products for the express purpose of interfering with Plaintiff's current and prospective business relationships.

65. As a result of Defendants' actions, Plaintiff has suffered and is continuing to suffer irreparable injury, including irreparable injury and damages, which includes a loss of sales and profits which Plaintiff would have made but for the acts committed in pursuance of the conspiracy.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that the Court enter judgment in its favor and grant the following relief:

A. Compensatory damages, consisting of general and special damages, in an amount to be proven at trial, including, but not limited to, treble damages pursuant to Va. Code § 18.2-500;

B. An award of punitive damages;

C. A preliminary and permanent injunction permanently enjoining Defendants and all others acting in privity or in concert with them from listing, marketing or offering for sale "Me-PB-Hyos" or other unauthorized PBA pharmaceuticals;

D. Reasonable attorney fees and costs in prosecuting this action as provided by § 35(a) of the Lanham Act, 15 U.S.C. § 1117 and Virginia law, including, but not limited to, Va. Code § 18.2-500;

E. Disgorgement of Defendants' profits from its unlawful acts and an accounting of such profit; and

F. Award Plaintiff such other relief as the interests of justice may require.

DATE: April 29, 2014

Respectfully submitted,

PBM PHARMACEUTICALS, INC.

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